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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,601	02/19/2002	Olga Bandman	PF-0544USN	2590

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,601	BANDMAN ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/20*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *21,22,30 and 32-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Applicant's amendment filed on 11/20/03 is acknowledged.

Claims 21-40 are pending in the application.

Election

2. Applicants elected with traverse, to prosecute Group II, which includes claims 23-29 and 31. (replacing original claims 3-12). Further, Applicants elect, with traverse, to prosecute claims related to the polynucleotide sequences encoding the polypeptide sequence of SEQ. ID.NO: 5, which sequences include SEQ. ID. NO: 11, and which sequences read on claims 23-29 and 31.

Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution. The traversal is on the ground(s) that unity of invention is present in all the claims, search and examination of the entire application would not be an undue burden. This is not found persuasive.

Applicant states that the unity of invention standard must be applied in national stage applications instead of U.S. restriction/election of species practice and reminds examiner Section 1850 of the Manual of Patent Examining Procedure (MPEP) under 35 U.S.C. 371, PCT Rule 13.1 and 13.2

It is the position of the examiner that the examiner applied the Unity of Invention standard PCT Rule 13.2 and did not apply U.S. restriction/election of species practice. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to nucleic acids, peptides, agonists and antagonist and various methods of using said products. However,

Mukerji et al disclose an isolated polynucleotide, SEQ.ID.NO: 8 encoding a polypeptide, which is 79.4% identical to an amino acid sequence SEQ.ID.NO: 5 of the instant invention (see the enclosed sequence alignment). Therefore, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

Invention nucleic acid (SEQ ID NO: 11) and Invention protein (SEQ ID NO: 5) are not so linked under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed nucleic acid and polypeptide share no common structure, no common function and no property. Therefore, where structural identity is required, such as for hybridization or expression of protein, each product appears to perform a different function in that peptides elicit a specific antibody response, nucleotides hybridize to DNA and antibodies bind to a specific binding site on antigen. Furthermore, they share no common structure, function and property so as to form a single general inventive concept under Rule 13.1 because Mukerji et al, (see the claimed sequence alignment with SEQ.ID.NO: 8) teach i.e., fragments of polypeptide SEQ.ID.NO: 5 and nucleic acid molecule that encodes said polypeptide, SEQ.ID.NO: 11. Hence, unity is lacking among nucleic acids and proteins.

Applicant states that Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case. Unity of Invention is accepted as between claims to peptide sequences and claims to the polynucleotide sequences which encode them and cites MPEP section 1893.03(d) at page 1800-149, column 2 ("[n] ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions. Applicant requests the Examiner to withdraw the Restriction Requirement at least as to claims 21-26, 31, 35, and 36, and examine those claims in a single application.

The examiner has carefully reviewed MPEP section 1893.03(d) at page 1800-149, column 2 examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions and established correctly the lack of unity. The technical feature of linking groups I-VII does not

constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art since Mukerji et al, (see the sequence alignment and SEQ.ID.NO: 8 of U.S.Patent No: 6, 428, 990) teach i.e., fragments of polypeptide SEQ.ID.NO: 5 and nucleic acid molecule, SEQ.ID.NO: 11 that encodes said polypeptide.

Further, applicant states Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend and cites MPEP section 1850(A) and 1893.03(d), Annex B (entitled "Unity of Invention"). Applicant states that claims 22-27, 35 and 36, all of which depend from claim 21, are all directed to compositions of matter, i.e., to products. All of these claims contain all of the features of the independent claim and there is unity of invention as between claim 21 and claim 31.

The examiner as indicated above the independent claim 1 (please note that restriction requirement imposed based on the originally presented claims) reads on the prior art and therefore, lacks unity of invention Hence, it is proper to restrict claims 21, 22, 35 and 36 (replacing original claims 1, 2, and 13) from claims 23-27 and 31 (replacing original claims 3-12), as stated in the Office action. Therefore, the Examiner rightly followed the lack of unity guidelines as stated above.

Applicant states that Unity of invention exists as between applicant's claims and provides MPEP 1850. Applicant states that the expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

Again, the examiner would like to bring applicant's attention to the lack of unity practice as unity of invention does not exist between claims because Mukerji et al, (see the sequence alignment and SEQ.ID.NO: 8 of U.S.Patent No: 6, 428, 990) teach i.e., fragments of polypeptide SEQ.ID.NO: 5 and nucleic acid molecule, SEQ.ID.NO: 11 that encodes said polypeptide. Therefore, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

Applicant states that the claimed polypeptide sequences, SEQ ID NO: 1-6 and the claimed polynucleotide sequences, SEQ ID NO: 7-12, which encode them, are corresponding technical features which are common to all of the claims and technically interrelate all of the claims. Thus, claims are linked to form a single general inventive concept and therefore Applicants are entitled to prosecute all of their pending claims in a single national stage application.

The examiner disagrees with the applicant because the common generic special technical feature does not link the DNA and polypeptide since they do not share a common structure or function or property as indicated above in holding of lack of unity. The DNA is made of nucleic acids and polypeptide is made of amino acids. Thus, these two products are not linked by the common generic special technical feature as defined by PCT Rule 13.2. Moreover, it is the position of the examiner that the expression "special technical feature" shall mean those technical features that define a contribution, which each of the claimed inventions, considered as a whole, makes over the prior art. However, Mukerji et al, 2002, U.S.Patent 6, 428, 990 teach i.e., fragments of polypeptide SEQ.ID.NO: 5 and nucleic acid molecule, SEQ.ID.NO: 11 that encodes said polypeptide. Therefore it does not constitute a special technical feature by definition. Therefore, lack of unity is present. Thus, it does not constitute a single inventive concept because DNA and protein shares no common structure or function or property. Therefore, it does not constitute special technical feature by definition and hence lack of unity exists with respect to independent claims.

Applicant states that In the event that the Examiner does not applv the unity of invention standard to this national phase application, claims 32-34 (replacing claims 7 and 8 of Group I) and claims 39 and 40 are drawn to methods of use of the polynucleotides of Group 11, and should be examined together and cites "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b) M.PE.P. 821.04.

The examiner applied the unity of invention standard to this national phase application as described above and further understands the Product and Process claims in light of In re

Ochiai, In re Brouwer and 35 U.S.C. § 103(b)". However, at present the product claims read on the prior art and are not yet in condition for allowance.

Applicant states that it is not proper to restrict Markush claims as set forth in the 7th edition of the M.P-E.P. (July 1998) at § 803.02 regarding restriction requirements in Markush-type claims. Further applicant asserts that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention and brings the Examiner's attention to the M.P.E.P. at § 803.04

As applicant states group I, i.e., Inventions SEQ.ID.NO: 1,2, 3,4, 5 and 6 are not linked by the common generic special technical feature involving an isolated polypeptide comprising a member selected from the group consisting of 1,2, 3,4, 5 and 6. Although the applicant's above concept may link the six SEQ.ID.NO1, 2, 3,4, 5 and 6 such concept does not constitute a special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a)) because applicant has not shown how these proteins are integrally related, what are those structural elements that are shared by these sequences and what is the common property. These sequences may share certain motifs and sequence similarity to oxidoreductase proteins, however, the Inventions SEQ.ID.NO: 1,2, 3,4, 5 and 6 share no common structure as represented by their amino acid sequences (for example, SEQ.ID.NO: 1 consists of 310 amino acids, SEQ.ID.NO: 5 consists of 444 amino acids etc) and are designated with specific sequence identification numbers such as HORP 1, HORP2, HORP3, HORP4, HORP5 and HORP 6. Further, the expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, Mukerji et al teach this concept i.e., fragments of polypeptide SEQ.ID.NO: 5 and nucleic acid molecule that encodes said polypeptide, SEQ.ID.NO: 11 (see the claimed sequence alignment with SEQ.ID.NO: 8 of U.S.Patent No: 6, 428, 990). Therefore, it does not constitute a special technical feature by definition. Therefore, lack of unity is present.

Applicants indicate that with respect to the election, they elect SEQ ID NO: 5 and 11. It is specifically noted, that a species election was not imposed. Each of the recited sequences is deemed structurally different from each other and applicants were required to elect a single sequence for examination on the merits. As such, examination of the single invention will be restricted to the nucleic acid of SEQ ID NO: 11 and the corresponding polypeptide SEQ.ID.NO: 5.

3. Claims 23-29 and 31 drawn to DNA are under prosecution with respect to SEQ.ID.NO: 11 and SEQ.ID.NO: 5. Therefore, applicant is advised to amend/restrict the claims to an isolated polynucleotide (SEQ.ID.NO: 11) encoding a peptide, SEQ.ID.NO: 5.

Status of Claims

4 Claims 21-40 are pending in the application.

Claims 23-29 and 31 drawn to DNA are under prosecution with respect to SEQ.ID.NO: 11 and SEQ.ID.NO: 5.

Claims 21-22, 30 and 32- 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Priority

5. This application is a national stage entry of PCT/US99/14711 06/29/1999 claims the benefit of Provisional Application 60091,177, 6/30/1998 and Provisional Application 60/155,241, 7/16/1998. The examiner has carefully examined the priority documents in support of the claimed invention. Claims 23-29 and 31, drawn to polynucleotide sequence (SEQ.ID.NO: 11) encoding the polypeptide sequence of SEQ.ID.NO: 5 that read on the elected claims 23-29 and 31. However, none of the priority documents show support for the polynucleotide sequence, SEQ.ID.NO: 11 with 3184 nucleotides encoding the polypeptide

sequence of SEQ.ID.NO: 5 having the 444 amino acids. Therefore, the benefit of the filing date of provisional applications has not been granted for the instantly examined claims.

Information Disclosure Statement

6. Information Disclosure Statement filed on 11/20/03 (Paper # 10) is acknowledged and a signed copy is attached to this Office action.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 23-29 and 31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

Claims 23-29 are drawn to an isolated polynucleotide encoding

(a) a polypeptide comprising an amino acid sequence SEQ.ID.NO: 5

(b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to SEQ.ID.NO: 5

(c) a biologically active fragment of a polypeptide having an amino acid sequence SEQ.ID.NO: 5.

(d) an immunogenic fragment of a polypeptide having an amino acid sequence SEQ.ID.NO: 5, an isolated polynucleotide encoding a peptide, SEQ.ID.NO: 5, an isolated polynucleotide comprising a polynucleotide sequence, SEQ.ID.NO: 11,a recombinant polynucleotide comprising a promoter sequence operably linked to a said polynucleotide, cell transformed with said recombinant polynucleotide and a method of producing said polypeptide.

Claim 31 is drawn to an isolated polynucleotide comprising:

(a) a polynucleotide comprising a polynucleotide sequence SEQ.ID.NO: 11

(b) A polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to SEQ.ID.NO: 11

(c) a polynucleotide complementary to a polynucleotide of (a)

(d) a polynucleotide complementary to a polynucleotide of (b) and

(e) an RNA equivalent of a)-d).

When determining whether an applicant has described the utility of invention, one has to determine whether the applicant has described a well-established utility. If not, has the application made any assertion of utility and whether the asserted utility is a specific and credible utility.

In the instant case, the applicant claims a polynucleotide that has SEQ.ID.NO: 11and other polynucloetide variants thereof that encode a certain polypeptide comprising SEQ.ID.NO: 5, biologically active fragments and immunogenic fragments. When the claims are interpreted in the light of the specification, the specification discloses that the invention relates to human oxidoreductase proteins (HORP 1-6) and polynucleotides that encode said polypeptides. However, the specification does not provide any disclosure as to how the polynucleotide encoding the claimed polypeptide relate to any known proteins. The specification on page16 discloses that the claimed cytochrome b5 /desaturase HORP-5 shares 23% identity with sunflower cytochrome b5 /desaturase fusion protein. The specification does not provide any disclosure as to how the polypeptide encoded by the claimed polynucleotide is related to any and all of these regulatory molecules. Further, the specification does not disclose the expression of this protein in any tissue of a given subject.

Even if homology of some kind is (23% identity) present, the issue becomes that just because the claimed sequence would have homology to a certain known polypeptide, would it also have the function of the known polypeptide. The specification does not disclose as to how similar or different the functions of the claimed polynucleotide encoded polypeptide would have been from that of the list of polypeptides disclosed in the specification. If the function of the polypeptide is not established, how can its utility be established or be specific? What criteria an artist would have used to determine whether the function of claimed polynucleotide encoding polypeptide is similar or different to that of the full-length polypeptides disclosed in the specification?

In light of the issue of function of the claimed polynucleotides, question also arises what will be the utility of vectors, host cells, and membranes that comprise the claimed polynucleotide? Logically, one would ask if an artisan did not know the function of a polynucleotide sequence, how would the artisan have known the consequence of the expression or inhibition of expression of such a polynucleotide sequence. Additionally, how would an artisan treat a disease for which the etiology or symptoms are not known or it is not known what disease would have been caused by the polynucleotide or its encoded polypeptide. Likewise how would an artisan have screened for compounds that affect the function of a polypeptide if the artisan had not known the function of the polypeptide. Furthermore, if the function of a protein is not established, what would have been the use and basis for developing an assay system?

Claims 23-29 and 31 in the currently written form, would encompass all the polynucleotides and variants thereof from all the living organisms that would encode a protein that would have had at least 10% or more sequence identity with SEQ. ID NO: 5. However, the specification does not provide any description what these sequences would have been that would have encoded all these proteins form all the living organisms, or how different or similar they would have been

from the SEQ. ID NO: 5 and SEQ.ID.NO: 11. It is, therefore concluded that because the function of the SEQ. ID NO: 11 is not disclosed, the credibility of the asserted utilities for the claims 23-29 and31 cannot be assessed.

In the event that the rejection under 35 USC 101 might be overcome, the following grounds of rejection would still apply. Claims 23-29 and 31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23-29 and 31 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the revised guidelines on written description available at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

The claims are discussed supra in Paragraph # 8.

The specification only describes a polynucleotide sequence of SEQ ID NO: 11. The specification describes as part of the invention-isolated polynucleotide encoding the polypeptide of SEQ ID NO: 5, which is described as Human oxidoreductase polypeptide HORP 5. However, broadly claimed nucleic acid sequence which encodes a polypeptide which is at least 90% identical to amino acid sequence to SEQ.ID.NO: 5, biologically active fragments or immunogenic fragments of said nucleic acid (The examiner considers them as variants and will be addressed as variants in the Office action) are not set forth in this specification. Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides by use of language in which a specified percent of amino acids can be changed. As depending from these are the vectors, host cells, vaccines, diagnostics and methods of producing the polypeptide. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116) The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 11 which corresponds to the polynucleic acid sequence encoding the polypeptide SEQ ID N0: 5. Thus, an isolated polynucleotide sequence consisting of SEQ ID NO: 11 and an isolated polynucleotide that encodes the polypeptide SEQ.ID.NO: 5 meet the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The claimed properties of the polynucleotide that encodes such protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability

(i.e. the instant fragments) and testing each to determine whether it encodes a protein having the particularly disclosed properties. As noted in the Guidelines at Section I.A (2). There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention from its function. There is no written description support for such variants as claimed.

Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicants invention as disclosed. The protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus between the structure of a gene sequence and the structure of the protein encoded, and the function of that encoded protein. However, similar function cannot be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number polypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide consisting of SEQ ID NO: 11 and an isolated polynucleotide encoding the SEQ ID NO: 5, fragments thereof and associated, vectors, vaccines, fusions etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless

of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

11. Claims 23-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To decide whether a specification is enabling, it is to be determined whether the specification discloses sufficient guidelines for successful making and using of the claimed invention without undue experimentation and whether sufficient examples have been provided. As described above (in written description rejection), the specification fails to describe sufficient guidelines for a skilled artisan to have practiced the invention as claimed without undue experimentation because the specification does not provide sufficient guidance for making and using the invention.

Claim Objections

12. Claims 23, 24,28 are objected to because of the following informalities: Claims 23, 24 and 28 are dependent on non-elected claims 21 and 22. Appropriate correction is required. For examination purposes, the examiner is reading the claim limitations of Claim 21 and 22 into claims 23, 24 and 28.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-29 and 31 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention,

Claim 23 is vague and indefinite in the recitation ' biologically active fragment' because it is unclear what is encompassed in this recitation. What constitutes a `biologically active fragment', and how much of the protein's original structure has to be retained such that the resulting protein can be considered as a` biologically active fragment', is not clear. The metes and bounds of the structure encompassed in the limitation ` biologically active fragment ' is indeterminate. Does a single amino acid, or a dipeptide qualify as a ` biologically active fragment'?

It is unclear in what way the protein is biologically active with respect to its immunogenicity or enzymatic activity? or other possible activities?

Claim 23 is vague and indefinite in the recitation: ' a naturally occurring amino acid sequence " because it is unclear what is encompassed in this recitation. What constitutes a naturally occurring amino acid sequence'?

Claim Rejections - 35 USC 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Please note that the priority is not granted for the reasons discussed in Paragraph # 2, Therefore, the filing date 6/30/1998 is not applicable for art rejections.

Claims 23-29 are drawn to an isolated polynucleotide encoding

(a) a polypeptide comprising an amino acid sequence SEQ.ID.NO: 5

(b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to SEQ.ID.NO: 5

(c) a biologically active fragment of a polypeptide having an amino acid sequence SEQ.ID.NO: 5.

(d) an immunogenic fragment of a polypeptide having an amino acid sequence

SEQ.ID.NO: 5, an isolated polynucleotide encoding a peptide, SEQ.ID.NO: 5, an isolated polynucleotide comprising a polynucleotide sequence, SEQ.ID.NO: 11,a recombinant polynucleotide comprising a promoter sequence operably linked to a said polynucleotide, cell transformed with said recombinant polynucleotide and a method of producing said polypeptide.

Claim 31 is drawn to an isolated polynucleotide comprising:

(a) a polynucleotide comprising a polynucleotide sequence SEQ.ID.NO: 11

(b) a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to SEQ.ID.NO: 11

(c) A polynucleotide complementary to a polynucleotide of (a)

(d) a polynucleotide complementary to a polynucleotide of (b) and

(e) an RNA equivalent of a)-d).

15. Claims 23-29 and 31 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Cho et al Accession number AF126799 or J.B.C. 1999, 274, 471-477.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948)* ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In *re Gray, 53 F. 2d 520, Il USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).*

Cho et al disclose an isolated polynucleotide encoding a polypeptide, which is 99.5% identical to an amino acid sequence SEQ.ID.NO: 5 of the instant invention (see the enclosed sequence alignment). Thus the disclosed polynucleotide encoding a polypeptide including fragments of said sequence, SEQ.ID.NO: 5 anticipated the instant claims. Further, the prior art discloses an isolated polynucleotide comprising a nucleotide sequence, which is 92.4% identical to the instant polynucleotide, SEQ.ID.NO: 11.

Since the Office does not have the facilities for examining and comparing applicant's claimed isolated polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipated the claimed invention.

16. Claims 23-29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Mukerji et al U.S.Patent 6,428,990 or 64,326,84.

Mukerji et al disclose an isolated polynucleotide, SEQ.ID.NO: 8 encoding a polypeptide, which is 79.4% identical to an amino acid sequence SEQ.ID.NO: 5 of the instant invention (see the enclosed sequence alignment). Thus the disclosed polynucleotide encoding a polypeptide including fragments of said sequence, SEQ.ID.NO: 5 anticipated the instant claims. Further, the prior art discloses an isolated polynucleotide (see the enclosed sequence alignment) comprising a nucleotide sequence, which is 60.9% identical to the instant polynucleotide, SEQ.ID.NO: 11 (see the enclosed sequence alignment). Since the Office does not have the facilities for examining and comparing applicant's claimed isolated polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430

(CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipated the claimed invention.

Remarks

17. No claims are allowed.

Conclusion

18. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

3/15/04

L.F.S.
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